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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,571	12/03/2001	Ian Tomlinson	8039/1125	6655

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PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,571	TOMLINSON ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-10,12-16 and 18-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/888,313.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/26/05 & 1/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 12/01/2005 is acknowledged and entered.

2. Claims 1-53 are pending.

Election/Restrictions

3. Claims 1-10, 12-16, and 18-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to ***nonelected inventions***, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/26/2004 and 02/03/2005.

Priority

4. This instant application is a CIP of 09/888,313 filed 06/22/2001, which claims benefit to a provisional application of 60/246,851 filed 11/08/2000. This instant application is granted the benefit of priority for 09/888,313 under 35 U.S.C. 120 and for 60/246,851 under 35 U.S.C. 119(e).

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/888,313, filed on 09/25/2003.

Information Disclosure Statement

6. The information disclosure statements (IDS) filed on 09/26/2005 and 01/30/2006 have been reviewed, and its references have been considered as noted on PTO-1449 form(s).

7. Claims 11 and 17 are under consideration in this Office Action.

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 11, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 11, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al. (US Patent 5,677,195) and Wagner et al. (US Patent 6,329,209 B1).

Response to Arguments

12. Applicant's arguments directed to the rejection under 35 U.S.C. 112, second paragraph, as being indefinite for claims 11, and 17 have been fully considered but they are not persuasive for the following reasons.

a. The limitation that the "*first and second repertoires of single chain polypeptides are present on a solid surface in a first and second series of continuous, non-intersecting lines, respectively, such that each line of said first series intersects with each line of said second series, such that members of the first repertoire are juxtaposed members of the second repertoire*" of claim 11 is vague because it is unclear the intersection of the lines would generate a two-chain polypeptide. As claimed, the array format is  wherein the lines on the x-axis is the "*first repertoires of single chain polypeptides*" and the lines on the y-axis is the "*second repertoires of single chain polypeptides*", and the intersection of the lines would result in a single amino acid interaction of the polypeptide chains. Thus, the limitation that the "*first and second repertoires of single chain polypeptides are present on a solid surface in a first and second series of continuous, non-intersecting lines, respectively, such that each line of said first series intersects with each line of said second series, such that members of the first repertoire are juxtaposed members of the second repertoire*" is vague.

b. The limitation that the "*first, second, and third repertoires Of single chain polypeptides are present on a solid surface in a first, second, and third series of continuous, non-intersecting lines, respectively, such that each line of said first series intersects with each line of said second and third series, each line of said second series intersects with each line of said first and third series, and each line of said third series intersects with said first and second series, such that members of the first, second and third repertoires are juxtaposed to each other*" of claim 17 is vague because it is unclear the intersection of the lines would generate a three-chain polypeptide. As claimed, the array format is  wherein the lines on the x-axis is the "*first repertoires of single chain polypeptides*" and the lines on the y-axis is the "*second repertoires of single chain polypeptides*", and the lines on the z-axis or lines that are 'diagonal' to the x-axis or y-axis is the "*third repertoires of single chain polypeptides*". The intersection of these lines would result in a single amino acid interaction of the polypeptide chains. Thus, the limitation that the "*first, second, and third repertoires of single chain polypeptides are present on a solid surface in a first, second, and third series of continuous, non-intersecting lines, respectively, such that each line of said first series intersects with each line of said second and third series, each line of said second series intersects with each line of said first and third series, and each line of said third series intersects with said first and second series, such that members of the first, second and third repertoires are juxtaposed to each other*" is vague.

Applicant alleges that claims 11 and 17 is not vague and indefinite because '*the scope and meaning of the instantly claimed invention is clear and unambiguous and the claims do not encompass a scenario in which the amino acid residues of a given member polypeptide are physically arranged in the form of a line*'. Thus, the rejection should be withdrawn.

Applicant's arguments are not convincing since claims 11 and 17 is vague and indefinite because as claimed in the instant claimed methods the series of lines are "***continuous, non-intersecting lines***" and they "***intersects***" is broad such that would not be unreasonable to

interpret the instant claims to encompass the interpretation that the intersection of the lines would result in a single amino acid interaction of the polypeptide chains. Moreover, the claim language that is "***continuous, non-intersecting lines***" and the mode of 'interaction' that is they "***intersects***," contradict each other such that it is unclear as to what is being claimed. Therefore, claims 11 and 17 is vague and indefinite, and the rejections are maintained.

13. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Winkler et al. (US Patent 5,677,195) and Wagner et al. (US Patent 6,329,209 B1) for claims 11, and 17 were considered but they are not persuasive for the following reasons.

Winkler et al. disclose a method and device for forming large arrays of polymers on a substrate (see e.g. Abstract; col. 2, lines 15-55; col. 2, line 63 thru col. 3, line 10; col. 7, lines 50-55). Winkler et al. disclose to different method for forming large arrays of polymers on a substrate, which are the flow channel method and the "spotting" method (see e.g. col. 8, lines 64 thru col. 10, line 12; figs. 1, 7 (A and B), and 11A). The flow channel method comprises a) providing a substrate comprises a plurality of channel paths form on the x-axis of the substrate and a plurality of channel paths form on the y-axis of the substrate, b) flowing the first reagents along the plurality of channel paths form on the x-axis of the substrate for immobilization of the reagent onto the substrate, c) flowing the second reagents along the plurality of channel paths form on the y-axis of the substrate for the 'coupling' of the second reagent with the first reagent at the intersection of the two channel paths, i.e. the channel paths form on the x-axis and the channel paths form on the y-axis, d) forming the large arrays of polymers at selected regions on a substrate (see e.g. col. 8, lines 64 thru col. 10, line 12; col. 10, line 14 thru col. 11, lines 63; figs. 1, 7 (A and B), and 11A). Additionally, Winkler et al. disclose a method wherein small "strips" of reagents are applied to the substrate by stripping the substrate with a pipettor (see e.g. col. 14, lines 10-15). The substrate includes materials such polystyrene in the form of gels, pads, or sheets (see e.g. col. 10, lines 17-26; col. 14, lines 45-49). The reagents include biological material such as peptides (see e.g. col. 5, lines 32-41; col. 8, lines 8-11).

The method of Winkler et al. differs from the presently claimed invention by failing to include immobilizing a single chain polypeptide on the solid support.

Wagner et al. disclose an array of protein capture agents on a solid support and the method of forming the array of protein capture agents on a solid support (see e.g. Abstract; col. 2, line 63 thru col. 3, line 9; col. 3, line 58 thru col. 4, line 2; col. 9, lines 58-65). The method of forming the array of protein capture agents on a solid support comprises the step of immobilizing the protein capture agents on a solid support via spotting method such as microprinting techniques and ink-jet printing technique (see e.g. col. 3, line 58 thru col. 4, line 2; col. 23, lines 10-37). The type of protein capture agents includes biological materials such as protein fragments and antibody fragments (see e.g. col. 4, lines 48-67; col. 5, line 34 thru col. 6, line 40).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include immobilizing a single chain polypeptide on the solid support as taught by Wagner et al. in the method of Winkler et al. One of ordinary skill in the art would have been motivated to include immobilizing a single chain polypeptide on the solid support in the method of Winkler et al. for the advantage of providing a rapid methods of preparing diverse polymer arrays with less processing step (Winkler: col. 11, lines 21-63) since both Winkler et al. and Wagner et al. disclose the spotting method for forming an array of polymers (Winkler: col. 9, lines 59 thru col. 10, line 12;Wagner: col. 23, lines 10-37). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Winkler et al. and Wagner et al. because Winkler et al. disclose that the striping method, i.e. forming lines on the substrate, is similar to the spotting method (Winkler:

col. 14, lines 10-15). Thus the methodology of forming spots or lines on the substrate would be a choice of experimental design and is considered within the purview of the cited prior art.

Applicant contends that the combine reference of Winkler et al. and Wagner et al. is not obvious over the instant claimed method because neither Winkler et al. nor Wagner et al. teach or suggest the "*method for generating polypeptide libraries of two- or three-chain polypeptides from separate repertoires of single-chain polypeptide*".

Applicant's arguments are not convincing since the combine teachings of Winkler et al. and Wagner et al. do render the method of the instant claims *prima facie* obvious. It is the examiner position that the method of Wagner et al. does disclose the use of '*single-chain polypeptide*' (see e.g. col. 6, lines 10-13; col. 13, lines 13-20) and forming fusion protein, i.e. '*two- or three-chain polypeptides*', (see e.g. col. 23, lines 57-59). Therefore, the combine teachings of Winkler et al. and Wagner et al. do render the method of the instant claims *prima facie* obvious, and the rejection is maintained.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
March 6, 2006